

PATENT COOPERATION TREATY
FILE COPY 210

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Form PCT/ISA/210 (first sheet) (July 1998) **DO NOT MAIL**

| | | |
|-------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|
| Applicant's or agent's file reference 7682-049-228 | FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below. | |
| International application No. PCT/US01/09091 | International filing date (<i>day/month/year</i>) 21 MARCH 2001 | (Earliest) Priority Date (<i>day/month/year</i>) 21 MARCH 2000 |
| Applicant AVIRON | | |

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of ____ sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).
- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing:
- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

2. ☒ **Certain claims were found unsearchable** (See Box I).

3. ☒ **Unity of invention is lacking** (See Box II).

4. With regard to the **title**,

- ☒ the text is approved as submitted by the applicant.
- ☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

- ☒ the text is approved as submitted by the applicant.
- ☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. ____

- ☐ as suggested by the applicant.
- ☐ because the applicant failed to suggest a figure.
- ☒ None of the figures.

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Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☒ Claims Nos.: 22
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Please See Extra Sheet.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☒ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
1-6, 17-19, 20 and species glycine, alanine, valine
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
☒ No protest accompanied the payment of additional search fees.

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Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

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International application No.
PCT/US01/09091

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A01N 63/00; A61K 39/155

US CL : 424/93.2, 211.1

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 424/93.2, 211.1

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

MEDLINE, BIOSIS, DERWENT, WEST

search terms: Parainfluenza virus, chimeric, hybrid, attenu?, bPIV3

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Y | WO 98/53078 A1 (THE GOVERNMENT OF THE UNITED STATES) 26 November 1998, see the claims. | 1-6, 17-20. |
| Y | US 5,869,036 A (BELSHE et al) 09 February 1999, see the claims. | 1-6, 17-20. |
| Y | SKIADOPOULOS et al. Three Amino Acid Substitutions in the L Protein of the Human Parainfluenza Virus Type 3 cp45 Live Attenuated Vaccine Candidate Contribute to Its Temperature-Sensitive and Attenuation Phenotypes. Journal of Virology. March 1998, Vol. 72, No. 3, pages 1762-1768, see the abstract. | 1-6, 17-20. |

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

| | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| * Special categories of cited documents: | "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention |
| "A" document defining the general state of the art which is not considered to be of particular relevance | "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone |
| "E" earlier document published on or after the international filing date | "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art |
| "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) | "&" document member of the same patent family |
| "O" document referring to an oral disclosure, use, exhibition or other means | |
| "P" document published prior to the international filing date but later than the priority date claimed | |

| | |
|--------------------------------------------------------------------------|----------------------------------------------------|
| Date of the actual completion of the international search 25 MAY 2001 | Date of mailing of the international search report |
|--------------------------------------------------------------------------|----------------------------------------------------|

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Y | TAO et al. Recovery of a Fully Viable Chimeric Human Parainfluenza Virus (PIV) Type 3 in Which the Hemagglutinin-Neuraminidase and Fusion Glycoproteins Have Been Replaced by Those of PIV Type 1. Journal of Virology. April 1998, Vol. 72, No. 4, pages 2955-2961, see the abstract. | 1-6, 17-20. |

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Information on patent family members

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International application No.

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BOX II. OBSERVATIONS WHERE UNITY OF INVENTION WAS LACKING

This ISA found multiple inventions as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I, claim(s) 1-6, drawn to chimeric parainfluenza virus comprising backbone bovine parainfluenza. (1st product)

Group II, claim(s) 7-11, drawn to a recombinant DNA or RNA chimeric parainfluenza virus. (2nd Product)

Group III, claim(s) 12-16, drawn to a vaccine formulation. (3rd product)

Group IV, claim(s) 17-19, and 20, drawn to a recombinant parainfluenza virus and vaccine. (4th product)

Group V, claim(s) 21, drawn to method of vaccinating.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack Unity of Invention because they are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for more than one species to be searched, the appropriate additional search fees must be paid. The species are as follows:

Amino acids as listed in claim 17 as each apply to position 1103 of L gene (total species 1-18).

The inventions listed as Groups I-V do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The invention of Group I does not make a contribution over the prior art as evidenced by The Government of the United States of America (WO 98/53078, 26 November 1998) see page 37, lines 2-10, and the claims. Since the invention is already known in the art thus the invention lacks unity of invention as defined by PCT Rule 13.2. The cited reference proves that the technical feature of Group I does not make a contribution over the prior art. The claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2 so as to form a single inventive concept, accordingly, the unity of invention is lacking among all groups.

The species listed above do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each amino acid residue at position 1103 (claim 17) confers different structure and presumably different effect on antigenicity and virulence of the virus. Since the effects of the substitutions are unpredictable, hence, each substitution is distinct.